RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	cenegermin-bkbj
Policy Number:	RxA.438
Drug(s) Applied:	Oxervate™
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Cenegermin-bkbj (Oxervate™) is recombinant human nerve growth factor (rhNGF). It is indicated for the treatment of neurotrophic keratitis.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Cenegermin-bkbj (Oxervate™)	Neurotrophic keratitis	1 drop in the affected eye(s) every 2 hours six times a day for 8 weeks	6 drops per affected eye per day

Dosage Forms

- Ophthalmic solution: 0.002% (20 mcg/mL)

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Neurotrophic Keratitis (must meet all)**:**

1. Diagnosis of stage 2 or 3 neurotrophic keratitis;
2. Prescribed by or in consultation with an ophthalmologist;
3. Age ≥ 2 years;
4. Dose does not exceed 1 vial per affected eye per day.

Approval Duration
Commercial: 8 weeks
Medicaid: 8 weeks

II. Continued Therapy Approval

A. Neurotrophic Keratitis (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 vial per affected eye per day.

Approval Duration
Commercial: 16 weeks (lifetime 2 courses of treatment)
Medicaid: 16 weeks (lifetime 2 courses of treatment)

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
rhNGF: Recombinant human nerve growth factor

APPENDIX B: Therapeutic Alternatives
- Not applicable

APPENDIX C: Contraindications/Boxed Warnings
- Contraindication(s):
  - None reported
- Boxed Warning(s):
  - None reported

APPENDIX D: General Information
- Definitions of neurotrophic keratitis stages 1-3:
  - Stage 1: Punctate keratopathy and/or corneal epithelial hyperplasia and irregularity.
  - Stage 2: Persistent corneal epithelial defect (PED), typically oval or circular in shape, with smooth and rolled edges.
  - Stage 3: Corneal stroma and a corneal ulcer is observed. Corneal ulceration tends to progress to perforation and/or stromal melting if not promptly and properly treated.

References
1. Oxervate Prescribing Information. Milan, Italy: Dompe farmaceutici S.p.A; October 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761094s000lbl.pdf. Accessed June 25, 2020.
2. European Medicines Agency, Science Medicines Health/Assessment Report. Available at: https://www.ema.europa.eu/documents/assessment-report/oxervate-epar-public-assessment- report_en.pdf. Updated May 18, 2017. Accessed June 25, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was updated. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving	06/25/2020	09/14/2020

medication that has been authorized by RxAdvance..." 5. Commercial approval duration and Medicaid approval duration updated. 6. Updated dosing regimen – eye to eye(s) 7. References were updated.		